ASPHALION
Knowledge from experience

SAFETY WRITING THROUGHOUT PRODUCT LIFECYCLE

High-quality safety documents to fulfill global regulatory requirements

Medicinal Products

ASPHALION
Knowledge from experience

Clinical development phase

Safety Management Plan

ASR

Annual Safety Report

Marketing authorisation preparation

RMP

Risk Management Plan

Post- Marketing phase

PSUR/PBRER

Periodic Safety Update Report
Periodic Risk Benefit Evaluation Report

ACO

Addendum to the Clinical Overview
Clinical Expert Statement

Signal detection report

Any Update of RMP

Any other safety report requested by authorities

Medical Devices

ASPHALION MedTech

Development → **Conformity assessment** → **Clinical Data** → **CE certification**

CDP	Clinical Development Plan
CIP	Clinical Investigation Plan
CIR	Clinical Investigation Report
RMP	Risk Management Plan / Risk Evaluation
CEP	Clinical Evaluation Plan
CER	Clinical Evaluation Report
PMS plan	Post Market Surveillance Plan
PMCF plan	Post-Market Clinical Follow-up Plan

CE certification → **Post Marketing Phase**

PMS report	(Class I devices)
PSUR	Periodic Safety Update Report (class II and class III devices)
PMCF report	Post Market Clinical Follow up Report
SSCP	Safety Summary and Clinical Procedures (class IIb implantable and class III devices)
RMP, CER and Plans updates	(PMS/ PMCF plans, CEP….)

Safety Reports
Clinical Development Phase

ASPHALION
Knowledge from experience

	Medicinal Products	Medical Devices
Type of report	Annual Safety Report (ASR)	Clinical Investigation Report
Frequency of preparation	Annually	< 1 year of the end of the clinical investigation < 3 months of the early termination or temporary halt
Regulation/ Guidelines	Regulation (EU) 536/2014	Regulation (EU) 2017/745
Content and Format	ICH E2F guideline on development safety update report	Commission Guidance on the content and structure of the summary of the investigation report (2023/C 163/06)
Submission	< 60 calendar days after DLP Submission through à Clinical Trials Information System (CTIS)	Submission through EUDAMED (when fully functional) In the meantime, submission via the respective national procedures, if applicable

Safety Reports
Post-marketing Phase

ASPHALION
Knowledge from experience

	Medicinal Products	Medical Devices
Type of report	Periodic Safety Update Report (PSUR)	Periodic Safety Update Report (PSUR)
Frequency of preparation	• According to the EURD list. • According to the condition laid down in the MA. • Standard submission schedule: • Product not marketed àevery 6 months since the product is authorized • Product marketed à every 6 months for 2 years, then once a year for the following 2 years and thereafter every 3 years • At Competent Authority request	• Class IIa: every 2 years • Class IIb: every year • Class III: every year
Regulation/ Guidelines	Regulation (EC) No 726/2004, Directive 2001/83/EC, Commission Implementing Regulation (EU) No 520/2012	Regulation (EU) 2017/745
Content and Format	Guideline on Good Pharmacovigilance Practices (GVP) Module VII – Periodic Safety Update Report	MDCG 2022-21 Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
Submission	• PSUR up to 12 months: < 70 calendar days after DLP • PSUR beyond 12 months: < 90 calendar days after DLP • At Competent Authority request: generally specified; otherwise, < 90 days after DLP • Submission through PSUR repository.	• Class III, Class IIa/IIb implantable: < 90 calendar days after DLP. Submission through EUDAMED (when fully functional). In the meantime, PSUR shall be available upon request. • No submission is required for Class IIa and Class IIb non-implantable. PSUR shall be available upon request.